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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/607,114	06/26/2003	Yu Ren	21068	3654
210	7590	11/17/2006	EXAMINER	
MERCK AND CO., INC			WARD, PAUL V	
P O BOX 2000			ART UNIT	
RAHWAY, NJ 07065-0907			PAPER NUMBER	
			1624	

DATE MAILED: 11/17/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/607,114

Applicant(s)

REN ET AL.

Examiner

PAUL V. WARD

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 August 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-53 is/are pending in the application.
- 4a) Of the above claim(s) 29-53 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-28 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- ☐ Notice of Informal Patent Application
- ☐ Other: _____

DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The rejections, of claims 1 and 24 under 35 U.S.C. 102, have been overcome by Applicant's amendment filed August 23, 2006.

Response to Amendment Regarding

2. **STATUS:** The rejection of claims 2-23 and 25-28 under 35 U.S.C. 103 set forth in the Office action dated May 19, 2006 has been maintained for the reasons of record for the reasons set forth herein.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bilodeau et al. (WO 01/17995).

Applicant claims salt forms of 4-[2-(5-cyano-thiazol-2-ylamino)-pyridin-4-ylmethyl]-piperazine-1-carboxylic acid methylamide as tyrosine kinase inhibitors. Additionally, Applicant claims different salts of 4-[2-(5-cyano-thiazol-2-ylamino)-pyridin-4-ylmethyl]-piperazine-1-carboxylic acid methylamide characterized by different X-ray powder diffraction patterns having different diffraction angles and melting endotherms.

Bilodeau discloses claims salt forms of 4-[2-(5-cyano-thiazol-2-ylamino)-pyridin-4-ylmethyl]-piperazine-1-carboxylic acid methylamide as tyrosine kinase inhibitors, which share the same formulaic compounds.

Bilodeau does not disclose 4-[2-(5-cyano-thiazol-2-ylamino)-pyridin-4-ylmethyl]-piperazine-1-carboxylic acid methylamide characterized by different X-ray powder diffraction patterns having different diffraction angles and melting endotherms, however, one skilled in the art would find the differences in the teaching to be negligible.

Thus, it would have been obvious to one of ordinary skill in the art at the time of invention to combine the teachings of Bilodeau to obtain the salt forms in the instant application. All of the moieties are taught in the art. Obviousness based on similarity of structure and functions entails motivation to make the claimed compound in expectation that compounds similar in structure will have similar properties. Therefore, one of ordinary skill in the art would be motivated to make the claimed compounds in searching for new salt forms with tyrosine kinase activity. See *In re Payne*, 203 USPQ 245 (CCPA 1979). Since Applicant's claims are prima facie obvious in view of the teachings of Bilodeau, Applicant's claims are rejected under 35 U.S.C. § 103.

Applicant's arguments filed August 23, 2006 have been fully considered but they are not persuasive. Applicant contends that the salt forms have an unexpected advantage, and thus, have an unexpectedly superior oral activity profile. However, Applicant's arguments are misplaced.

Bilodeau discloses claims salt forms of 4-[2-(5-cyano-thiazol-2-ylamino)-pyridin-4-ylmethyl]-piperazine-1-carboxylic acid methylamide as tyrosine kinase inhibitors.

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Applicant claims different salts of 4-[2-(5-cyano-thiazol-2-ylamino)-pyridin-4-ylmethyl]-piperazine-1-carboxylic acid methylamide characterized by different X-ray powder diffraction patterns having different diffraction angles and melting endotherms. It would have been obvious to one of ordinary skill in the art at the time of invention to combine the teachings of Bilodeau to obtain the salt forms in the instant application. All of the moieties are taught in the art. Obviousness based on similarity of structure and functions entails motivation to make the claimed compound in expectation that compounds similar in structure will have similar properties. Therefore, one of ordinary skill in the art would be motivated to make the claimed compounds in searching for new salt forms with tyrosine kinase activity. See *In re Payne*, 203 USPQ 245 (CCPA 1979). Since Applicant's claims are prima facie obvious in view of the teachings of Bilodeau, Applicant's claims are rejected under 35 U.S.C. § 103.

Conclusion

Claims 1-24 are pending. Claims 1-24 are rejected. No claims are allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of


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the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to PAUL V WARD whose telephone number is 571-272-2909. The examiner can normally be reached on M-F 8 am to 4 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O Wilson can be reached on 571-272-0661. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



James O. Wilson
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Technology Center 1600